

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

In re. PHARMACEUTICAL INDUSTRY	)	MDL No. 1456
AVERAGE WHOLESALE PRICE	)	Civil Action No. 01-12257-PBS
LITIGATION	)	
	)	Hon. Patti Saris
THIS DOCUMENT RELATES TO THE	)	
AMENDED MASTER CONSOLIDATED	)	
CLASS ACTION	)	
	)	

**FIFTH STATUS REPORT OF UNITED STATES DEPARTMENT OF  
HEALTH AND HUMAN SERVICES CONCERNING SUBPOENAS  
FOR MEDICARE BENEFICIARY DATA, TRACKS 1 & 2**

The United States Department of Health and Human Services (HHS), through its undersigned counsel, respectfully submits this fifth report to the Court concerning the status of the production of Medicare beneficiary information. This report addresses data requested by the plaintiffs' subpoena duces tecum dated June 6, 2006,<sup>1</sup> which seeks Medicare beneficiary information relevant to the drugs at issue with respect to Track 1, Class 1, and data requested by the plaintiffs' second subpoena served by the plaintiffs on or about August 4, 2006, concerning drugs at issue in Track 2. The HHS also reports briefly on a separate request made by the Track 1 defendants for testimony of former HHS employees.

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<sup>1</sup> This subpoena was erroneously referred to in earlier status reports as being dated June 19, 2006.

1. Track 1 Subpoena

The Centers for Medicare & Medicaid Services (CMS) has completed most of the work involved in producing the Track 1 beneficiary data responsive to the June 6, 2006, subpoena. The agency anticipates completing the project within the next five days or so. As reported previously, the processing of the request proceeded at a faster pace than originally predicted in part because the extraction of data from the 1991 - 1997 data files coincidentally was ready to begin at a time when the mainframe computer system was available to process against those files.

The CMS notes that, from the beginning, the agency has stated that plaintiffs must pay for the costs incurred by the agency in producing the data – estimated at approximately \$109,000. Counsel for the plaintiffs has made no objection to this condition. By letter dated August 9, 2006, the CMS wrote to plaintiffs' counsel, Edward Notargiacomo, requesting that he sign a letter reflecting the agreement to pay the CMS costs. Despite at least one follow-up reminders, the plaintiffs' counsel has not returned an executed letter. CMS will not release the data until it receives a signed letter of agreement to pay the costs.

2. Track 2 Subpoena

With regard to the plaintiff's August 4, 2006, subpoena regarding the Track 2 drugs, the HHS previously advised plaintiffs that it can provide the data by March 1, 2007. The CMS continues work on processing this request. The relevant drug codes have been submitted for the matches against the carrier, outpatient, and durable medical

equipment data, and most of the finder files have been extracted. However, significant additional work remains, including merging finder files, eliminating duplicate beneficiary information, and developing one final finder file to process against the enrollment data file so that a final list of names and addresses can be generated. This additional work will take some time, and it appears that the processing of the Track 2 data request will not progress as fast as the Track 1 request, in part because of conflicting resource demands, due to Part D re-enrollment. However, CMS still believes it will be able to produce the Track 2 data by March 1, 2007.

3. Additional Request by Track 1 Defendants

By letter dated September 26, 2006, the Track 1 defendants submitted to CMS a request, pursuant to HHS's *Touhy* regulation at 45 C.F.R. § 2.4, seeking the testimony of three former HHS employees at the Track 1, Class 2 trial in November 2006. The three former employees are: Nancy-Ann Min DeParle, the HCFA Administrator and Deputy Administrator from 1997 - 2000; Thomas Scully, the CMS Administrator from 2001 to 2003; and Stanley Weintraub, a Senior Policy Advisor at CMS from 1984 to 1998.

According to the defendants' request, these former employees "would testify to their knowledge or understanding of the use of AWP for reimbursement, the relationship between AWP and provider acquisition cost, the extent to which reimbursement for drug ingredients operated as a cross-subsidy for the inadequate reimbursement of the costs of service and administration, the reasons for maintaining AWP as part of the Medicare reimbursement, and the general operation of the reimbursement system." The defendants'

letter asked that CMS provide a substantive response to the Track 1 defendants' request by October 15, 2006, in light of the upcoming trial scheduled to commence November 6, 2006. As of this writing, the CMS has not made a final decision. However, a recommendation concerning the request is now before Leslie Norwalk, Acting Administrator of the Centers for Medicare & Medicaid Services, and a final decision is anticipated shortly.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above "Fourth Status Report of United States Department of Health and Human Services Concerning Subpoenas For Medicare Beneficiary Data, Tracks 1 & 2" to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

Dated: October 16, 2006

/s/ George B. Henderson, II  
George B. Henderson, II